Universitätsklinik Balgrist, Zürich
Klinik für Chiropraktische Medizin
Direktor: Prof. Dr. Armin Curt

Betreuung der Masterarbeit: Prof. Dr. Cindy Peterson
Leitung der Masterarbeit: Prof. Dr. Kim Humphreys

Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.

Ethics Approval and Study Protocol

Masterarbeit
zur Erlangung des akademischen Grades
Master of Chiropractic Medicine (M Chiro Med)
der Medizinischen Fakultät der Universität Zürich

vorgelegt von
Patric Beereuter (10-751-303)

2017

1. Summary (German)

Unser Gleichgewicht ist für die Bewältigung des Alltags sehr wichtig. Bei sportlichen Aktivitäten wird der Anspruch wesentlich erhöht. Um die Balance zu halten, muss unser Gehirn somatosensorische, visuelle und vestibuläre Inputs verarbeiten und dementsprechende Signale für den Ausgleich an unseren Körper senden. Falls jemand Probleme mit dem Gleichgewicht hat, kann eine dieser drei Inputs beeinträchtigt sein. In der Klinik ist es wichtig, das Ausmass der Beeinträchtigung zu messen. Empfehlenswerte Tests fordern das Gleichgewicht auf verschiedenen Stufen heraus, indem diese drei Inputs einzeln ausgeschaltet oder verändert werden. So wird beispielsweise beim Schliessen der Augen der visuelle Input an das Nervensystem deaktiviert. Das Gehirn muss sich nunmehr ganz auf den somatosensorischen Afferenzen von den Füssen am Boden und den vestibulären Input aus unserem Gleichgewichtsorgan verlassen und den fehlende neurologische Information dementsprechend kompensieren. Beim Stand auf einer Schaumstoffmatte wird entsprechend der somatosensorische Input verändert. Das Balance Error Scoring System (BESS) schafft somit durch die Kombination aus Stand auf der Schaumstoffmatte und gleichzeitigem Schliessen der Augen eine zusätzliche Schwierigkeitsstufe.

Das Balance Error Scoring System (BESS) ist ein vergleichsweise einfacher, nicht instrumentengestützter Test, der von Klinikern und Forschern verwendet wird, um die Balance zu evaluieren. Es gibt viele unterschiedliche Studien, die sich mit der Reliabilität und Validität dieses Testes befassen, jedoch kaum Berichte über alternative objektive Gleichgewichtsmessungen, die ohne die teils subjektiven und von der Erfahrung des Testers abhängigen Bewertungskriterien anwendbar sind. Ebensolche Messmethoden, wie zum Beispiel der Sensory Organization Test (SOT) von Neurocom oder andere Messungen unter Verwendung von Druckmessplatten sind sehr teuer und nicht immer verfügbar.

Das Ziel dieser Studie ist es herauszufinden, ob die kostenlose Iphone-Applikation «Advanced Gyroscope» eine objektive Messmethode für das Gleichgewicht ist, die anstatt des BESS Protokolls eingesetzt werden kann und nicht dessen beschriebene Einschränkungen in Bezug auf die Inter- und Intra-Tester Reliabilität teilt. Falls das Gyroscope App zuverlässige Resultate liefern kann, könnte es in der Klinik und für Sportvereine (z.B. Eishockey) ein einfaches Hilfsmittel zum Messen des Gleichgewichtes werden. Mit diesem App könnte man auch einen Baseline-Test mit dem ganzen Team durchführen und im Falle einer Hirnerschütterung einsetzen, um Veränderungen der Balance objektiv zu erfassen und zu quantifizieren.

Abbreviations

BESS	Balance error scoring system
mBESS	Modified BESS
SOT	Sensory organisation test
SCAT-5	Sport concussion assessment tool 5

2. Explanatory Notes

2.1. Introduction

Balance is crucial for activities of daily living. To maintain static balance somatosensory, visual and vestibular feedback are necessary (1, 2). A deficit in one of those inputs can lead to balance disturbances. To test the degree of the deficit in clinical testing, one of those inputs can be altered. Visual feedback for example can easily be removed by having the person close their eyes. Altering the proprioceptive input can be done by using a foam surface. Testing the balance is especial important in cases of concussions since this condition accounts for 10 to 15% of all sport related injuries (3-5). Postural deficits is one of the many symptoms of concussion (5, 6) and can best be detected within the first 72 hours after an incident (7). So far, there is no specific treatment to prevent prolonged symptoms after a concussion (8). Therefore, it is important to have an easy and reliable method to detect concussions quickly.

To measure a person's balance, there are high technical and low technical methods (2). On the top of the range of high technical methods is the Sensory Organisation Test (SOT) developed by Nashner and Peters (1). It is designed to systematically disrupt the sensory selection process by altering available somatosensory or visual information, or both, while measuring a subject's ability to minimize postural sway. The most used low technical method is the Balance Error Scoring System (BESS). It is a useful and widely used tool by clinicians and researchers to evaluate postural stability. A modified version of the BESS (mBESS), without the use of the foam pad, is part of the Sport Concussion Assessment Tool 5th Edition (SCAT5) (9).

There are many studies on how to perform a BESS and on its reliability but there are few other options to test the postural stability in a quick, easy and cost-effective way. Could the Advanced Gyroscope App be such an option?

2.2. Material and Methods

2.2.1. Study

For our study we are going to need 50 volunteers that meet our inclusion criteria as stated in the study protocol. Each person will be asked to perform a BESS Protocol with an iPhone attached to their waist with the Advanced Gyroscope Application running at the same time. The balance testing regime consists three stances on two different surfaces. The three stances are double leg stance, single leg stance and tandem stance. Each stance will be performed on a firm surface and on a foam surface. To perform the BESS protocol, a foam pad such as the Airex BeBalanced foam pad is needed which has been purchased and sponsored by the first author (chiropractic medicine student Patric Beereuter). To measure the movements during the protocol a flip case and iPhone with gyroscope are needed. For this purpose, I (Chiro med student Patric Beereuter) would use my already possessed iPhone 5s and flip case. The Advanced Gyroscope Application was downloaded for free from the Apple App Store. More detailed information on how each participant will be tested can be found in the study protocol in chapter 3.

2.2.2. Literature Review

To know what has been done so far it was necessary to do a literature review. Because our study includes the broad subject of balance disorders and the diagnosing of such by using the BESS and various technology, we chose a narrative literature review to find the most related papers for our subject. Therefore, it cannot be counted as being complete. The search on PubMed and PMC included the terms Balance Error Scoring System, balance, balance disorders, postural sway, postural stability, gyroscope, mobile technology, concussion, force plate and SOT in various combinations.

2.2.3. Ethics Approval and Study Protocol

BASEC Nr.: 2017-01354.

Before starting the study, we had to get permission from the local ethics committee, KEK Zürich. The required study protocol together with the cover letter, signature pages and participant information in both English and German were submitted online using BASEC. Permission to start the study was given at the end of October 2017.

2.2.4. Results

There are no results that can be drawn directly from the study as of yet, because it has not been started. However, the literature review has already shown some results that can help us in understanding to further progress our study.

For this study it is for example important to know that the BESS is a widely used and more importantly useful tool to assess static balance, showing moderate to good reliability (7). The inter-tester reliability was classified as good (10) and the test-retest reliability moderate (7, 10, 11). To improve the reliability, it is recommended to administer a series of three BESS and average the results (12). Therefore, we also chose to do three trials of the BESS protocol. Good evidence has been found for the use of high technological force plates like the SOT and the correlation with the BESS (2, 13, 14). There has also been a study to compare the SOT with an iPad2 based accelerometer and it has been shown to produce enough quantity and quality of data to accurately evaluate postural stability (15, 16). Very few studies have been conducted using mobile devices with gyroscopic measurements. The results range from not being able to detect a concussion (17), to delivering sensitive and objective measurements of balance in addition to the BESS (15, 18).

2.3. Discussion

Since the study to compare the balance testing of the BESS with the data from the Advanced Gyroscope App has not yet been started there are no direct results to discuss so far.

Even though the studies that have been done on this matter so far have been inconsistent, they have also shown promise. Some studies have shown gyroscopic measurements are indeed able to keep up with high sophisticated equipment like the SOT and 3D Motion Capture that are used in well-equipped Clinics (15, 16, 19).

Gyroscopic measurements like the Advance Gyroscope App could potentially be more sensitive in detecting balance disturbances compared to the Balance Error Scoring System which does not rely on technology. Some studies however came to the conclusion that it is not possible to distinguish between healthy and concussed participants using balance accelerometer whereas the BESS could do so (17).

2.4. Conclusion

Since balance plays such a great role in our daily life, it is crucial to be able to detect disturbances. In some sports the risk is high of getting a concussion that can lead, among other issues, to balance problems. A quick, reliable and cost-effective method to detect such must be found. The idea of using mobile technology, which nowadays is always available, is an option that should be considered and deserves and needs much more research. It is still a far distance from having a good mobile application and easy to use equipment to putting it into clinical practice.

2.5. Personal contribution

The literature review, ethics approval and the study protocol have been designed and written by me, Patric Beereuter, with the kind advisory assistance of Prof. Dr. Cynthia Peterson and Dr. Alexander Ruhe from Wolfsburg, Germany. Since Dr. Ruhe has much experience in diagnosing and treating patients with balance disorders and concussions and has published on this topic himself, Prof. Peterson suggested that I involve him in the planning and in the further course of conducting the study. To begin with, I travelled to Wolfsburg to see what he has done so far and how he uses high sophisticated balance boards and the Balance Error Scoring System to diagnose and monitor patients. He is also working together with a professional ice hockey club of the German professional ice hockey league Deutsche Eishockey Liga, the Wolfsburg Grizzlys. He is a pioneer in trying to find more cost effective and easier to use methods for diagnosing balance disorders. He introduced me to the iPhone app Advanced Gyroscope and showed me how we might be able to use it for this specific topic. The literature review included in the study protocol has been written solely by me and has been reviewed by Prof. Dr. Peterson and Dr. Ruhe. To be able to conduct this study we had to write an ethics approval and a study protocol which both have been done by me. The submission to the KEK was done online through BASEC. After the first submission the required changes have been carried out by me and contact with the responsible people from the Ethics Committee has always been through me with a “carbon copy” to the study involved people. I am the author of the additional documents such as the cover letter and patient information in English and German.

2.6. References for Summary and Explanatory Notes

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3. Ethics Approval and Study Protocol

Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.

This document is the research plan template for research projects involving either humans or data or biological samples from humans except clinical trials. For clinical trials pursuant to ClinO please refer to the respective protocol template available at swissethics: Clinical Protocol template for IIT (Investigator initiated Trials) studies.

This template is suitable for research projects:

- performed in Switzerland and
- where the Swiss law on human research (Federal Act on Research involving Human Beings (HRA)) and its ordinance HRO (Human Research Ordinance, Ordinance on Human Research with the Exception of Clinical Trials) applies and
- are human research projects with the exception of clinical trials (HRO Art. 6), e.g. where the research project does not relate to a project in which persons are prospectively assigned to a health-related intervention in order to investigate its effects on health or on the structure and function of the human body (HRA Art. 3l) and
- where biological material is sampled and/or health-related personal data is collected (prospectively) and/or make further use for research (i.e. for not yet determined research projects, HRO Art.6)

Swissethics strongly recommends using this template when writing plans / study protocols for research projects meeting these criteria to be submitted to ethics committees and if applicable to Swiss authorities. The project plan can be submitted in English as well as in the respective local language of the relevant authority. The template shall be applied correspondingly.

The current template is based on:

- AGEK – CT CER / Swissmedic guidelines: “Studienprotokolle von klinischen, Investigator-initiated’ Studien/Versuchen / Exigences des protocoles d’études/d’essais cliniques initiés par l’investigateur” dated 24.02.2009,
- the Federal Act on Research involving Human Beings (HRA) and its applicable ordinance Ordinance on Human Research with the Exception of Clinical Trials (HRO) and
- the STROBE statement
- the Essentials of Good Epidemiological Practice (EGEP)
- swissethics checklists for research project submissions

Note:

- *instructions* are indicated in *blue italics*, they need to be deleted (or alternatively may be formatted as “hidden Text” that will not show in printing).
- Template text formatted in **regular type red** provide reference to the legal requirements. This text may be deleted.
- Section headings and template text formatted in regular type (black) should be included in the project plan document as provided in the template.
- Header and footer should contain the following information (on all pages): [Research Project Title], [Page x of xx], [version x, DD/MM/YYYY], [Project ID].
- The template needs to be adapted to the individual projects.
- In places where the information is redundant, it is acceptable to refer to another section, to document or to state its redundancy but the section must not be deleted.

Refer questions regarding use of this research plan template to swissethics (info@swissethics.ch, phone: +41 (41) 440 26 67, www.swissethics.ch).

This template was adapted from the template for clinical trial protocols that was developed by a task force initiated by the Federal Office of Public Health (FOPH) and swissethics (former AGEK) in 2013 and under the lead and coordination of the Swiss Clinical Trial Organisation (SCTO).

Clinical research experts from different institutions reviewed the present template. The FOPH and swissethics (former AGEK) reviewed the template and recommend its use.

Contributors to this template and reviewers (alphabethic):

- CHUV/PMU Lausanne, Dr Reto Auer
- CHUV/IUMSP Lausanne and Cochrane Switzerland, Dr Bernard Burnand
- CHUV/IUMSP Lausanne and Cochrane Switzerland, Dr Erik von Elm
- EOC Ticino, Dr Stephany Fulda
- EOC Ticino, Dr Liliane Petrini
- HUG/CRC Geneva, Dr Christophe Combescure
- HUG and CCER (Ethics Committee) Geneva, Prof Dr Bernard Hirschel
- Swiss Paraplegic Centre Nottwil, Dr Angela Frotzler
- SAKK and Charité Universitätsmedizin Berlin, PD Dr Pirus Ghadjar
- SCTO Basel, Annette Magnin
- SCTO Basel, Dr Caecilia Schmid
- USZ/CTC Zurich, Dr Eva Brombacher
- USZ Zurich, Dr Cédric Poyet

3.1. Research Plan BESS vs. Gyroscope

Type of Research Project:	Research project in which health-related personal data is collected
Risk Categorisation:	A
Project Identifier:	Uniklinik Balgrist
Project Leader:	*Prof. Dr. Kim Humphreys* *Head Chiropractic Medicine* *University of Zürich Hospital Balgrist* *Forchstrasse 340, 8008 Zürich* *0041443865702*
Health condition / problem:	To begin with this study will only look at healthy individuals to obtain base line comparative data. The purpose is to determine which method is more reliable. Main conditions we want to evaluate in the future would be people with mild traumatic brain injuries (i.e. mTBI in Hockey players).
Project Duration:	The first volunteers would be performing the tests on the 13.1.2018. The project should be ended by the 31.10.2018.
Project Plan Version and Date:	Version number 2, 20.09.2017

Signature Page

Project number N/A

Project Title Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.

The project leader and the methodologist Prof. Dr. Kim Humphreys have approved the research plan version 2 (dated 20.09.2017), and confirm hereby to conduct the project according to the plan, the current version of the World Medical Association Declaration of Helsinki and the local legally applicable requirements.

Project Leader: Barry Kim Humphreys, Professor and Head Chiropractic Medicine

Scottsdale, USA 10.10.2017 _____

Place/Date Signature

Project Methodologist Barry Kim Humphreys, Professor and Head Chiropractic Medicine:

Scottsdale USA 10.10.2017 _____

Place/Date Signature

Table of Contents (Only of the Study Protocol)

3.1.1. Synopsis (Summary in local language)

Unser Gleichgewicht ist für die Bewältigung des Alltags sehr wichtig. Bei sportlichen Aktivitäten wird der Anspruch wesentlich erhöht. Um die Balance zu halten, muss unser Gehirn somatosensorische, visuelle und vestibuläre Inputs verarbeiten und dementsprechende Signale für den Ausgleich an unseren Körper senden. Falls jemand Probleme mit dem Gleichgewicht hat, kann eine dieser drei Inputs beeinträchtigt sein. In der Klinik ist es wichtig, das Ausmass der Beeinträchtigung zu messen. Empfehlenswerte Tests fordern das Gleichgewicht auf verschiedenen Stufen heraus, indem diese drei Inputs einzeln ausgeschaltet oder verändert werden. So wird beispielsweise beim Schliessen der Augen der visuelle Input an das Nervensystem deaktiviert. Das Gehirn muss sich nunmehr ganz auf den somatosensorischen Afferenzen von den Füssen am Boden und den vestibulären Input aus unserem Gleichgewichtsorgan verlassen und den fehlende neurologische Information dementsprechend kompensieren. Beim Stand auf einer Schaumstoffmatte wird entsprechend der somatosensorische Input verändert. Das Balance Error Scoring System (BESS) schafft somit durch die Kombination aus Stand auf der Schaumstoffmatte und gleichzeitigem Schliessen der Augen eine zusätzliche Schwierigkeitsstufe.

Das Balance Error Scoring System (BESS) ist ein vergleichsweise einfacher, nicht instrumentengestützter Test, der von Klinikern und Forschern verwendet wird, um die Balance zu evaluieren. Es gibt viele unterschiedliche Studien, die sich mit der Reliabilität und Validität dieses Testes befassen, jedoch kaum Berichte über alternative objektive Gleichgewichtsmessungen, die ohne die teils subjektiven und von der Erfahrung des Testers abhängigen Bewertungskriterien anwendbar sind. Ebensolche Messmethoden, wie zum Beispiel der Sensory Organization Test (SOT) von Neurocom oder andere Messungen unter Verwendung von Druckmessplatten sind sehr teuer und nicht immer verfügbar.

Das Ziel dieser Studie ist es herauszufinden, ob die kostenlose Iphone-Applikation «Advanced Gyroscope» eine objektive Messmethode für das Gleichgewicht ist, die anstatt des BESS Protokolls eingesetzt werden kann und nicht dessen beschriebene Einschränkungen in Bezug auf die Inter- und Intra-Tester Reliabilität teilt. Falls das Gyroscope App zuverlässige Resultate liefern kann, könnte es in der Klinik und für Sportvereine (z.B. Eishockey) ein einfaches Hilfsmittel zum Messen des Gleichgewichtes werden. Mit diesem App könnte man auch einen Baseline-Test mit dem ganzen Team durchführen und im Falle einer Hirnerschütterung einsetzen, um Veränderungen der Balance objektiv zu erfassen und zu quantifizieren.

Project Leader (or Sponsor)	Prof. Dr. Kim Humphreys Head Chiropractic Medicine University of Zürich Hospital Balgrist Forchstrasse 340, 8008 Zürich 00414438657012
Project Title:	Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.

Short Title / Project ID:	BESS vs. Gyroscope
Project Plan Version and Date:	Version 02, 20.9.2017
Risk categorisation:	A
Type of Research:	Research project in which health-related personal data is collected. Coded data is used with no identifying features.
Project design:	Observational
Background and Rationale:	Provide a short background and the rationale for the research project, this includes the health condition / problem studied.
Objective(s):	To compare the concurrent validity of the BESS (Balance Error Scoring System) with the Advanced Gyroscope iPhone Application in measuring postural stability.
Endpoint(s):	All measurements are done in one appointment. There are no outcome measurements.
Inclusion / Exclusion criteria:	Inclusion criteria: • Person needs to be willing to participate as a volunteer. • Participant needs to be able to follow a BESS protocol. • No history of concussion in the last 6 months. • No known neurological disorder or no known muscosceletal injury, condition or surgery that would affect their balance. • No knee or ankle injury in the previours six months. Exlusion criteria: • History of concussion in the last 6 months. • Known neurological complaints such as vestibular disorders. • Known muscosceletal injury, condition or surgery that would affect their balance. • Knee or ankle injury in the previours six months.
Project assessments, procedures:	With each volunteer, we are going to perform 3 trials of the Balance Error Scoring System (BESS) protocol and at the same time they have to wear an iPhone attached to their waist with the Adanced Gyroscope Application running. For each BESS the Volunteer has to perform a total of six stances with eyes closed for 20 seconds each. 3 on firm surface and 3 on a Airex BeBalanced foam pad. The stances are: Double Leg Stance, Single Leg Stance, Tandem Stance. We will assess the Errors during each stance and compare the score to the measurements the Gyroscope App will produce at the same time.
Number of Participants:	50

Project Duration, schedule:	The first volunteers would be performing the tests on the 13.1.2018. The project should be ended by the 31.10.2018
Project Centre(s):	Single-centred (Universitätsklinik Balgrist, Zürich)
Statistical Considerations:	A total of 50 volunteers. Concurrent validity. Test-retest reliability: ICC Absolute Reliability: SEM Correlation between the two methods: Pearson's correlation coefficient and Bland-Altman plot The Redcap data management system will be used. Data will be analysed by SPSS software.
Other methodological Considerations:	N/A If applicable describe here other methodological considerations than statistical, e.g. epidemiological, qualitative methods.
Risk-Benefit statement:	There are many people who suffer from loss of postural stability. Many of those cases are due to mild traumatic brain injuries, often from a fall or due to sports injuries. The BESS is a widely-used tool to document the degree of postural stability. The Problem with it is that tends to be subjective and the interexaminar reliability is less than desirable. We are hoping that the Advanced Gyroscope App could give reliable data that could be collected easily and anywhere. In addition to that the free Application would offer a cheaper option to force plates which measure the same thing. The balance exercises are very easy to conduct minimal risk.

Abbreviations

DoH	Declaration of Helsinki
EC	Ethics Committee
EGEP	Essentials of Good Epidemiological Practice
FOPH	Federal Office for Public Health
HRA	Federal Act on Research involving Human Beings (Human Research Act, HRA)
HRO	Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO)
ID	Identification
IIT	Investigator-initiated Trial
SE	Serious event
STROBE	Strengthening the reporting of observational studies in epidemiology
BESS	Balance Error Scoring System

3.1.2. Schedule of Assessments (Flow of Research Project)

Procedure	Patient or Examiner action	Time
1. Patient Information and Informed Consent	Examiner notes the required patient information: • Age, Gender, Weight, Height, Sports • Inclusion criteria Patient reads and signs the Informed Consent document.	5 min
2. Explanation of the BESS protocol and Gyroscope iPhone Application	Examiner hands over the BESS Information sheet with the stances and scoring explanation answers questions to the protocol and explains how the Gyroscope measurements work.	5 min
3. Conducting the BESS protocol ➔ 3 times ➔ each stance 20 seconds with eyes closed and hand on hips ➔ Examiner starts the Gyro measurement before each stance	3 stances on hard surface (floor): • Double Leg Stance • Single Leg Stance • Tandem Stance 3 stances on soft surface (foam) • Double Leg Stance • Single Leg Stance • Tandem Stance	3 x 5min 15 min
4. Termination of Study	Patient may ask questions or have a look at the results if requested.	5 min
Total Duration		***Approx. 30 min***

3.2. Administrative Structure

Sponsor, Project Leader and Coordinating researcher (if identical)	Name: *Prof. Dr. Kim Humphreys* Address: *Forchstrasse 340* Email: *kim.humphreys@balgrist.ch* Phone: *0041443865702* Fax: *0041443861589*
Project site(s) and responsible researcher:	Institution: *Universitätsklinik Balgrist* Name: *Prof. Dr. Kim Humphreys* Address: *Forchstrasse 340* Email: *kim.humphreys@balgrist.ch* Phone: 00414438657012
Key Persons involved in research project:	Name: *Cand. Med. Patric Beereuter* Address: *Unterweid 1, 8926 Uerzlikon* Email: *patric.beereuter@gmail.com* Phone: *0041765739080* Name: *Prof. Dr. Cynthia Peterson* Address: *Forchstrasse 340* Email: *xraydcpeterson@yahoo.ca* Phone: 00414438657012 Name: *Dr. Alexander Ruhe* Address: *Porschestrasse 1,* *38440 Wolfsburg, Germany* Email: *alexander_ruhe@hotmail.com*

3.3. Ethical and Regulatory Aspects

3.3.1. Ethical Conduct of Study

Commencement of this research project is conditional of the documented decision of the EC (and if applicable the FOPH) concerning the conduct of the project. The research project shall only begin once approval from all required authorities has been received. Any additional requirements imposed by the authorities shall be implemented. Provide a statement of seeking the necessary approvals.

e.g. “The research project will be carried out in accordance to the research plan and with principles enunciated in the current version of the Declaration of Helsinki (DoH), the Essentials of Good Epidemiological Practice issued by Public Health Schweiz (EGEP), the Swiss Law and Swiss regulatory authority’s requirements as applicable. The EC and regulatory authorities (FOPH if radiation sources are involved) will be informed about project start and termination.

3.3.2. Risk categorisation

The risk category is A. There is minimal risk to the volunteers.

3.3.3. Ethics Committee (EC) and Competent Authorities (CA), FOPH

No data will be collected prior to Ethics Approval. In case of termination or early stopping of the study the KEK will be informed within 90 days.

3.3.4. Participant Information and Informed Consent

The investigators will explain to the participant the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. The participant will be informed that the participation in the study is voluntary and that he/she may withdraw from the study at any time.

The participant for the study will be provided a participant information sheet and a consent form describing the study and providing sufficient information for participant to make an informed decision about their participation in the study.

The participant information sheet and the consent form will be submitted to the CEC and to the competent authority (as applicable) to be reviewed and approved. The formal consent of a participant, using the approved consent form, must be obtained before the participant is submitted to any study procedure.

The participant should read and consider the statement before signing and dating the informed consent form, and should be given a copy of the signed document.

3.3.5. Participant privacy and safety

The Project Leader affirms and upholds the principle of the participants' right to dignity, privacy and health and that the project team shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals.

Individual participant medical information obtained as a result of this research project is considered confidential and disclosure to third parties is prohibited. Participant confidentiality will be further ensured by utilising identification code numbers to correspond to medical information in the computer files.

For data verification purposes, authorised representatives of the Sponsor, a competent authority (e.g. FOPH), or an ethics committee may require direct access to parts of the medical records relevant to the project, including participants' medical history.

3.3.6. Early termination of project

Because each examination only takes approximately 30 minutes, there is no real reason for early termination except if a person does not feel comfortable during one of the stances with closed eyes they have to do.

3.3.7. Amendments, Changes

There should not be any significant changes during the course of the project. If there are significant changes throughout the course of this study the KEK will be asked for permission before implementing the changes.

3.4. Literature Review

3.4.1. Background

Abstract

The Balance Error Scoring System (BESS) is a useful and widely used tool by clinicians and researchers to evaluate postural stability. There are many studies on how to perform a BESS and on its reliability but there are few other options to test the postural stability in a quick, easy and cost-effective way. Such an option could be the Advanced Gyroscope App.

This article gives an overview of the most commonly used high-technology and low technology methods to test balance, show their strengths and weaknesses and presents potential new methods along with their research evidence which has been conducted done so far.

Furthermore, this study will present a new, low cost technology called the Advanced Gyroscope iPhone Application that could improve or at least support the balance assessment. Therefore the purpose of this study will be to compare the concurrent validity of the BESS (Balance Error Scoring System) with the Advanced Gyroscope iPhone Application in measuring postural stability.

Abbreviations

BESS	Balance error scoring system
mBESS	Modified BESS
SOT	Sensory organisation test
CDP	Computerized surround posturography
COP	Centre of pressure
COM	Centre of mass
SCAT-5	Sport concussion assessment tool 5
DS	Double leg stance
TS	Tandem stance
SLS	Single leg stance

Introduction / Review of the Literature

Postural stability and balance are crucial in activities of daily living and even more so in sports. Somatosensory, visual and vestibular feedback are necessary to be able to maintain static balance (1, 2, 20). If someone experiences a deficit in one of those input sources the balance can be affected. For the clinicians, it is important to be able to quantify the magnitude of the deficit. Recommended tests challenge the balance system on different levels. To put a person's postural stability to the test one of the three inputs stated above can be altered. For example, by closing the eyes the visual feedback is removed, whereas by standing on a foam pad the proprioceptive feedback from the feet to the central nervous system is altered.

Testing the balance is specifically important in cases of concussion since this condition accounts for 10-15% of all sports-related injuries (3-5). The 5th consensus statement on concussion in Berlin in 2016 states that balance impairment is one of the symptoms to look for in a concussed athlete (5, 6, 21). Research has shown that there is postural deficit after a concussion and that it is detectable during the first 72 hours after the incident (7). Since there is no specific treatment or prevention of prolonged symptoms for an acute concussion (8), it is crucial to have an easy, valid and reliable tool to detect concussions quickly. There are high technical and low technical ways to measure a person's balance (2).

Sensory Organisation Test (SOT)

It is common and widely validated for the application in sports related concussion to look at the sway area or velocity using force plates (20). The most commonly used

technical balance test in concussion research is the Sensory Organisation Test (SOT) developed by Nashner and Peters (1). It is designed to disrupt the sensory selection process by altering visual or somatosensory information, or both and measure the reaction forces produced by the body's centre of pressure (COP) during involuntary sway (22). This means it is measuring a subject's ability to minimize postural sway. The person is told to maintain upright position. Therefore, it tests the ability to minimalize postural sway. Throughout the test sway referencing is used because the platform beneath the patient's feet and the environmental surround move according to the patient's anterior-posterior sway. Sway referencing involves tilting the support surface or visual surround to follow the patient's centre of gravity sway (20).

Definition of centre of pressure: "COP can be defined as the position of the global ground reaction force vector that accommodates the sway of the body. In simple terms, it is the point at which the pressure of the body over the soles of the feet would be if it were concentrated in one spot. This measure, however, is not a true record of body sway but rather a measure of the activity of the motor system in moving the COP (23)."

For the SOT the subjects stand on dual-force plates in a 3 sides surround posturography (CDP) system. They are asked to stand as motionless as possible with their feet shoulder-width apart. The SOT uses 6 different conditions which are each performed 3 times to assess balance (Figure 1). Each condition consisting of three twenty second trials (2).

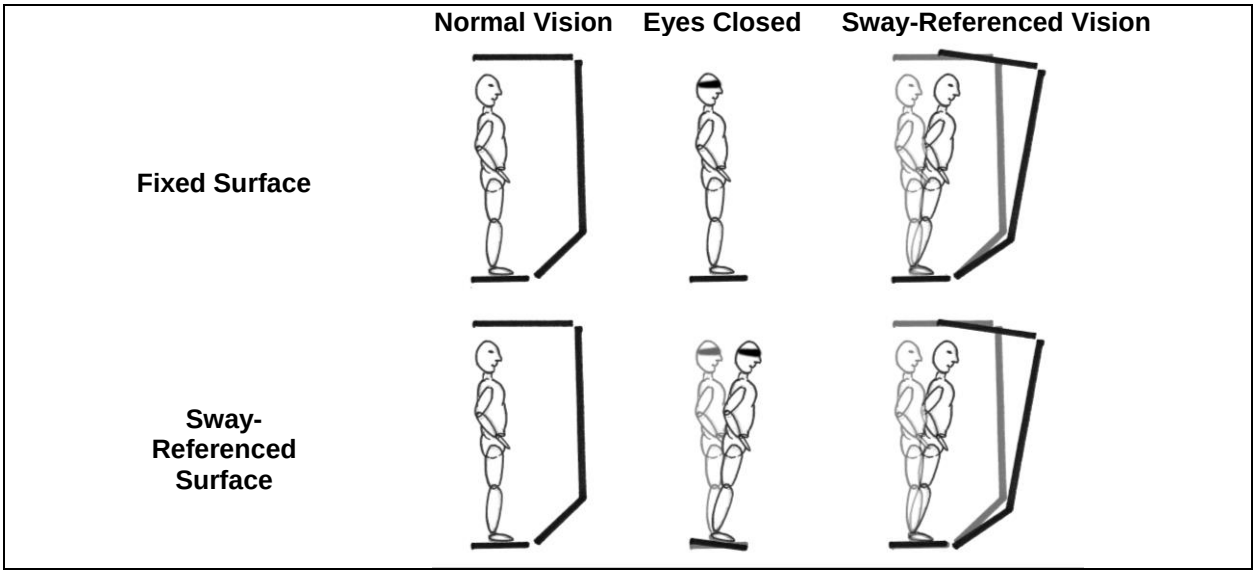
The 6 conditions include:

- Eyes open on firm surface
- Eyes closed on firm surface
- Eyes open with sway referenced visual surround (altered vision)
- Eyes open on sway referenced support surface (unsteady surface)
- Eyes closed on sway referenced support surface
- Eyes open on sway referenced support surface and surround (unsteady surface and altered vision)

The SOT can assess the ability to ignore the inaccurate information from the sway referenced senses. An overall composite equilibrium score describing a person's level of performance is calculated. Higher scores equal better balance.

The use of force platforms as a high technology method to measure balance has good evidence and has also been correlated with the BESS (2, 13, 14). Overall, the SOT shows only moderate reliability with strongly varying results for the 6 different conditions (22). There has also been a study to compare the SOT with an iPad2 based accelerometer and it has been shown to produce enough quantity and quality of data to accurately evaluate postural stability (15, 16). Research has shown that deficits on average last 3 to 5 days after a concussion (18, 20, 24), but also that the SOT can detect balance impairments up to 10 days (18, 25) post-concussion. Even though the SOT is a very useful tool to detect balance impairments, it has limited availability and is significantly more expensive than any low technology balance assessment method.

Figure 1: Explanatory Table of the Sensory Organisation Test (SOT) used with the Neuro-Com Smart Balance Master (Image: P.Beereuter)



Balance Error Scoring System (BESS)

High technical devices such as force plates are often not accessible for clinicians when needed and therefore the low technical methods like the Balance Error Scoring System (BESS) serve as a suitable replacement (11,12). Due to its cost-effectiveness the BESS is currently the most used clinical balance assessment tool following concussion (13, 26). The BESS consists of single and double leg standing balance tests with eyes open or closed on two separate surfaces. It only requires a foam pad and a stop watch and can therefore be used anywhere and is quick and easy to conduct (figure 2).

Developed by the University of North Carolina-Chapel Hill the BESS system provides a cost-effective and sport-related assessment for balance (2). The BESS is widely accepted by researchers as an adequate test for assessing balance deficits in a concussed individual (2, 7, 14, 27). The balance testing regime consists of three stances on two different surfaces. The three stances are double leg stance (DS), single leg stance (SLS) and tandem stance (TS). Each stance is performed on a firm surface and on a foam surface such as the “Airex BeBalanced” foam pad. The person’s stance should consist of the hands on the iliac crest, eyes closed and a consistent foot position depending on the stance. The participants do not wear shoes. Each stance needs to be maintained for 20 seconds. The examiner counts the number of errors (deviation) from the proper stance.

Counted as an error is:

- Moving the hands off the hips
- Opening the eyes
- Step, stumble or fall
- Abduction or flexion of the hip beyond 30°
- Lifting the forefoot or heel off the testing surface
- Remaining out of the proper testing position for more than 5 seconds

The maximum number of errors for a single stance is 10. The total maximum is 60. If multiple errors are committed simultaneously, only one error is counted. The foam pad creates an unstable surface therefore making the balance task more difficult.

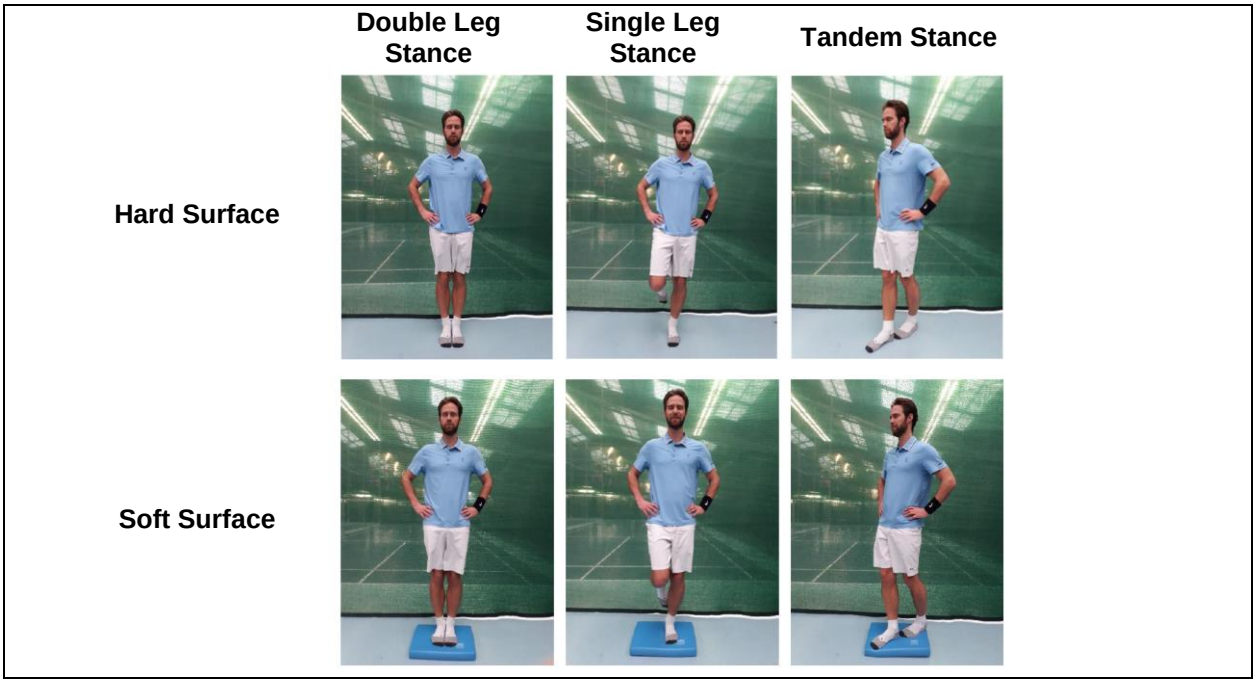
There is a modified version of the BESS (mBESS) without the use of the foam pad which is part of the Sport Concussion Assessment Tool 5th Edition (SCAT5) (6, 21). It only consists of the three stances on a firm surface with the same criteria applying as in the full BESS protocol but with a maximum of 30 error points. The mBESS has shown good reliability (28). However, research has shown that the sensitivity to chronic post-concussive syndrome is greater when instrumented with an inertial sensor using accelerometer and gyroscope measures at the centre of mass (COM) (29).

Definition of Centre of Mass: “COM is a point equivalent of the total body mass in the global reference system and is commonly accepted to lie around the S2 vertebral level in normal upright posture (23).”

Overall the BESS has moderate to good reliability to assess static balance (7, 13). Mostly, the inter-tester reliability was classified as good(10) and the test-retest reliability moderate (7, 10, 11). To improve the reliability it is recommended to administer a series of three BESS and average the results (12).

A weakness of the BESS is that it is not able to differentiate between fatigue and concussion related influence on balance if tested within the first 20 minutes of an incidence (7). As with any balance measures, the BESS scores also increase with functional ankle instability (30), external ankle bracing (31) and increasing age (32). People undergoing a neuromuscular training show lower BESS scores (33) and healthy athletes can demonstrate a subtle learning effect on the BESS when the retest intervals are too short (34, 35). No learning effects were noticed in a recent study performed on children between 9 and 14 years of age (10). Additionally high technology balance testing devices were able to differentiate between concussed people with and without headache (36) whereas the standard BESS could not (37).

Figure 2: How to administer the BESS (Picture: P. Beereuter, demonstrated by M. Ehrler)



New Methods to assess postural stability

In recent years there have been studies to find new, cost-effective, easy to conduct and fast methods to detect balance disturbances (15, 19, 29, 38). The aim is to be as objective as possible and to get a high interrater reliability and high validity. The National Collegiate Athletic Association has adopted the Wii Fit for Nintendo as an alternate method (14). The newest research states that accompanied by the appropriate analytic software, the Wii Balance Board may be an alternative for assessing postural stability in concussed student-athletes (38, 39). However, more research is needed on this subject since not all agree that a cheaper technical device can be a serious alternative to the high technology force plates (26).

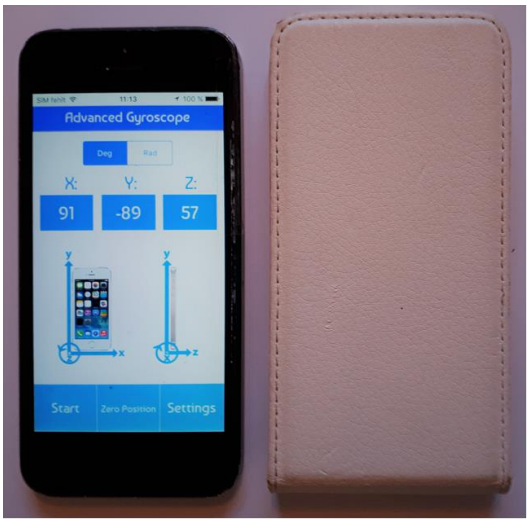
Just a handful of studies have been done using small mobile devices with a gyroscope or accelerometer to compare the measures to the BESS. The ones that have been done have shown conflicting results ranging from not being able to detect a concussed individual (17) to showing great promise to deliver a sensitive and objective measure of balance in addition to the BESS (15, 26).

Another potential cost-effective option could be the free iPhone Application “Advanced Gyroscope” by Nicolas Mercier.

Advanced Gyroscope Application (iPhone) (40)

The Advanced Gyroscope is a free iPhone application developed by Nicolas Mercier. This application can measure records of angular positions, velocities and acceleration of the iPhone and export this data to the computer (figure 3).

Figure 3: iPhone 5s with the Advanced Gyroscope App (40) running and Flipcase used to attach the Mobile Device to the Patient (Picture: P. Beereuter)



Features of the Advanced gyroscope (40):
In the main view:

- Read the angular position, in degrees or radians
- Set the initial position (zero position)

In the settings menu:

- Set the sampling frequency (up to 100 measurements / s)
- Set a countdown before the beginning of the measures
- Select the format of decimal numbers (. or ,)

In the export menu:

- Display measurement readings with date and time.
- Generate a .txt file showing angular position, velocity or acceleration
- Retrieve this file on iTunes and / or by email, then copy and paste the data to a spreadsheet software as Excel to use them.

Mobile Phones are getting more and more sophisticated, carrying multiple sensors. Accelerometers and gyroscopes are inertial sensors using The accelerometer is used to detect the orientation of the phone and the gyroscope tracks rotation or twist motion, thus adding another dimension. Accelerometers use linear acceleration of movement, whereas gyroscopes measure angular rotation velocity. They both measure the rate of change from the start value. In practice this means that to get accurate information over a phone's position you need the combined information from a 3-axis accelerometer and a 3-axis gyroscope (41).

Not enough research on this topic has been done and the results are inconsistent. The first studies done using accelerometer and gyroscopic measurements to quantify postural stability have shown that gyroscopic measurements can indeed be an objective and useful way to show balance deficits and can keep up with high technology equipment tests like the SOT or 3D Motion Capture (15, 16, 19). However, other studies came to the conclusion that balance accelerometer measurement was not able to distinguish between a concussed and a healthy participant whereas the BESS could do so (17).

Objective of the study

Because of the potential the gyroscopic measurements have and because there has not been enough research conducted on this topic, the objective of this study is to compare the concurrent validity of the BESS with the Advanced Gyroscope iPhone Application in measuring postural stability.

Three trials of the Balance Error Scoring System (BESS) protocol will be conducted while simultaneously the participants wear an iPhone attached to their waist with the Advanced Gyroscope Application running to measure the sway at the COM in degrees per second.

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Figures

3.4.2. Rationale for the research project

The aim is to find out whether or not the Advanced Gyroscope App could be a potential objective measurement for postural stability. The BESS Protocol is subjective and performed by different people would most likely produce different scores. If the Gyro App proves to be reliable and useful it could be beneficial to practices, sport teams (e.g. Ice Hockey) to have an objective way of measuring the postural stability. It might also be an option to do a baseline test in a team and in case of a concussion to do the same protocol and see if there has been an impact on the postural stability.

3.4.3. Risk-Benefit Assessment

For the participants, there is no immediate health benefit other than seeing whether or not they have a consistent postural stability. The benefit would come once they experience something that affects their postural stability. Then it would be possible to redo the protocol and see if there has been a change.

3.5. Objectives, Outcomes and other Study Variables

3.5.1. Objectives

The objective is to compare the concurrent validity of the BESS (Balance Error Scoring System) with the Advanced Gyroscope iPhone Application in measuring postural stability.

3.5.2. Primary and secondary outcomes

The purpose of this study will be to compare the concurrent validity of the BESS (Balance Error Scoring System) with the Advanced Gyroscope iPhone Application in measuring postural stability.

3.5.3. Other study variables

Not applicable.

3.6. Project Design

3.6.1. Type of research and general project design

The study is an observational concurrent validity study.

3.6.2. Procedures

Each person will be asked to perform a BESS Protocol with an iPhone attached to their waist with the Advanced Gyroscope Application running at the same time. The iPhone will have a flipcase which will be inserted into the back of the trousers or belt of the volunteer. Before each trial there will be a calibration to “zero” process for the Gyroscope App. The duration of an examination should be about 30 minutes. The Balance Error Scoring System offers an easy way to measure postural stability. The balance testing regime consists three stances on two different surfaces. The three stances are double leg stance, single leg stance and tandem stance. Each of them will be performed on a firm surface and on a foam surface such as the Airex BeBalanced foam pad. The person’s stance should consist of the hands on the iliac crest, eyes closed and a consistent foot position depending on the stance. The participants will not wear shoes.

Each stance needs to be maintained for 20 seconds. The examiner counts the number of errors (deviation) from the proper stance. Counted as an error is:

- Moving the hands off the hips
- Opening the eyes
- Step, stumble or fall
- Abduction of flexion of the hip beyond 30°
- Lifting the forefoot of heel of the testing surface
- Remaining out of the proper testing position for more than 5 seconds

The maximum number of errors for a single stance is 10. The total maximum is 60. If multiple errors are committed simultaneously, only one error is counted.

At the same time, the Advanced Gyroscope App will be running on the iPhone. It measures the sway of a person from their neutral (starting) position of each stance. It measures deviation on the x, y and z axis with 10 measurements per second and in degrees per second. From all measures, the mean value will be calculated and produce a score for each stance. This way we can compare the BESS score to the Gyroscope score.

3.6.3. Recruitment and Screening

Participants are contacted by telephone or asked in person if they want to volunteer in this study. Participants will include Chiropractic Medicine students from the University of Zürich, friends from sports teams. The participant information letter will be handed over to the person for more insight when asked for participation and if they are interested in taking part.

3.6.4. Methods of minimising bias

To minimise the risk of getting different results on the BESS scores, it will always be the same person performing the data collection. This person will be Cand. Chiro. Med. Patric Beereuter.

3.7. Project Population

We will need about 50 participants for this study. Ideally, we want younger, healthy individuals and sports participants.

3.7.1. Inclusion criteria

The participant will be asked to give written informed consent to the experimental procedure, which is in accordance with the latest revision of the Declaration of Helsinki and approved by the ethics committee of the KEK Zurich.

The participant needs to be between the age of 14 and 60 and be willing to participate as a volunteer. The Participant needs to be able to follow a BESS protocol.

Other criteria are:

- No history of concussion in the last 6 months.
- No known neurological disorder or no known muscosceletal injury, condition or surgery that would affect their balance.
- No knee or ankle injury in the previous six months.

3.7.2. Exclusion criteria

We exclude people who have any positive answers on the inclusion criteria form.

Person doesn't meet the age criteria.

Volunteer has a history of concussion in the last 6 months, or a known neurological complaint such as vestibular disorders, or a known musculosceletal injury, condition or surgery that would affect their balance, or knee or ankle injury in the previous six months.

3.7.3. Criteria for withdrawal/discontinuation of participants

The volunteers are free to withdraw from this study during the procedure at any time if they feel any discomfort or if they do not want us to use their results in our research. They will not be asked to justify the reasons for withdrawing.

3.7.4. Project Assessments

The raw Gyroscope data will be transferred from the iPhone to the Computer and with a custom-made template transferred into Microsoft Excel where the mean value is calculated automatically. The mean values are transferred into a Microsoft Word file in which we filled in the BESS Score values for each person. This data will then be transferred to SPSS for statistical analysis.

Data will be stored in SPSS and a copy in the Chiropractic Medicine Research Office at the Chiropractic Department of the Uniklinik Balgrist.

3.7.5. Project flow chart/table of procedures and assessments

The following baseline characteristics will be assessed for each participant:
See: “SCHEDULE OF ASSESSMENTS”

3.7.6. Assessments of primary endpoints/outcomes

Not applicable as all measurements are done at the same timepoint.

3.7.7. Assessment of secondary endpoint/outcome(s)

There will be no additional measurements.

3.7.8. Assessment of other study variables

Not applicable.

3.7.9. Assessment of safety and reporting

There are no health hazards known that would require special measures.

3.7.10. Definition of Serious Events (SEs)

A **serious event** is any unfavourable event for which a causal relationship to sampling of biological material or the collection of health-related personal data cannot be ruled out, and which:

- requires hospitalisation or prolongation of an inpatients’ hospitalisation,
- results in persistent or significant disability or incapacity, or
- is life-threatening or results in death,

If a serious event occurs the research project will be set on hold.

3.7.11. Assessment and Documentation of SEs

The assessment by the project leader with regard to the project-specific measure relation is done according to the following definitions:
Unrelated: The occurrence of the event has no temporal relationship to the project-specific measures applied and can be explained by the underlying disease or other factors.

Related: There is a plausible temporal relationship between the occurrence of the event and the project-specific, applied measures and cannot be explained by the underlying disease or other factors.

All SEs are to be documented in the participants´ file and on the SE report form. A sample form is appended to the Protocol and can be downloaded at www.swissethics.ch.

3.7.12. Reporting of SEs, Safety and Protective Measures

The project leader shall report any occurring SE to the responsible EC within 7 days (and to the FOPH in case of involved radioactive sources). He/she shall also submit a report which evaluates the relationship between the event reported and the methods of collecting health related personal data or sampling of biological material within that project, furthermore proposals how to proceed with the project.

The project leader shall notify the EC within 7 days of any immediate other safety and protective measures, which have to be taken during the conduct of the research project. In addition, the project leader shall explain the circumstances, which necessitated the safety and protective measures.

3.8. Statistical Methodology

3.8.1. Determination of Sample Size

Minimal sample size is usually determined to be 30 subjects. In this study 50 Subjects will be included.

3.8.2. Data processing

The BESS produces a score for each stance and at the end a mean will be calculated. For the Gyroscope data, which is measured in degrees per second, we calculate a mean for each stance because there are 10 measurements per second. The mean value should give us an overview of how much a person sways during a stance and therefore gives us an idea of the person’s postural stability. The calculation will be transferred from raw Gyroscope data from the iPhone to the Computer and with a custom-made template transferred into Microsoft Excel where the mean value is calculated automatically. The mean values are transferred into a Microsoft Word file in which we filled in the BESS Score values for each person. This data will then be transferred to SPSS for statistical analysis. Therefore we can compare the values for each stance separately and also the overall value for the postural stability.

3.8.3. Planned analysis

A total of 50 volunteers.
Concurrent validity.
Test-retest reliability: ICC
Absolute Reliability: SEM
Correlation between the two methods: Pearson's correlation coefficient and Bland-Altman plot

3.8.4. Datasets to be analysed

The BESS vs. the Gyroscope.

3.8.5. Handling of missing data

There will be no missing data as we will be collecting data until we have 50 complete sets.

3.8.6. Ancillary analysis

Not applicable.

3.8.7. Deviations from the original statistical plan

The data will be tested for normal distribution prior to applying the statistical tests.

3.8.8. Data and Quality Management

The person collecting the data has been trained in the procedures and has performed several practice data collections on colleagues.

3.8.9. Data handling and record keeping/archiving

The idea is to enter all Data in REDCap system, provided by the Balgrist University Hospital.

All data contains no participants details and will be coded by assigning a number and stored on the Master student's computer and in the Chiropractic Medicine Department at the University of Zürich.

Excel and Word files used in this study will be filled in using track changes and regularly saved as non-editable PDF files to ensure traceability.

3.8.10. Confidentiality, Data Protection

All personal data collected within this study is strictly confidential. The volunteers will not be identified personally. All data will be analysed and presented as a group and not individual identifiable. The data will only be used for scientific publication or presentations. If requested, the ethic commission may have access to the original data. The volunteers name will never be published.

3.8.11. Coding

All data contains no participants details and will be coded by assigning a number and stored in the Chiropractic Medicine Department of University of Zürich at the Universitätskinik Balgrist. Only the Project leader will have access to the Key.

3.8.12. Archiving and Destruction

All informed consents and final data sets will be stored in the Chiropractic Medicine research department.

3.9. Publication and Dissemination Policy

3.9.1. Publication of results

The plan is to submit the final paper for publication as the Doktorarbeit.

3.9.2. Data sharing

They would have to contact the University of Zürich Chiropractic Medicine Department for access to the data set.

3.10. Funding and Support

The project is very inexpensive to conduct. For the BESS measurements, except from the Airex foam pad, no further equipment will be needed. For the Gyroscope measurements, the only things needed are: An iPhone (provided by the Researcher) attached to a belt or with a flip case, Advanced Gyroscope iPhone App (free) and a Airex BeBalanced foam Pad (80 CHF). There is no financial support to this project.

3.11. Insurance

This is a risk category A study. No incidents requiring insurance should occur. The Uniclinic Balgrist has a liability insurance for unpredictable events.

3.12. References

1. Declaration of Helsinki, Version October 2013, (http://www.wma.net/en/30publications/10policies/b3/index.html)
2. Essentials of Good Epidemiological Practice (EGEP; http://www.public-health.ch/logicio/client/publichealth/file/EGEP_en.pdf)
3. Humanforschungsgesetz, HFG Bundesgesetz über die Forschung am Menschen (Bundesgesetz über die Forschung am Menschen, HFG) vom 30. September 2011/ Loi fédérale relative à la recherche sur l'être humain (loi relative à la recherche sur l'être humain, LRH) du 30 septembre 2011. (http://www.bag.admin.ch/themen/medizin/00701/00702/07558/index.html?lang=de)
4. Verordnung über die Humanforschung mit Ausnahme der klinischen Versuche (Humanforschungsverordnung, HFV) / Ordonnance relative à la recherche sur l'être humain à l'exception des essais cliniques (Ordonnance relative à la recherche sur l'être humain, ORH) / Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) (http://www.admin.ch/opc/en/classified-compilation/20121177/index.html)
5. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, et al. (2007) The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies. PLoS Med 4(10): e296. doi:10.1371/journal.pmed.0040296
6. Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, et al. (2007) Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. PLoS Med 4(10): e297. doi:10.1371/journal.pmed.0040297
7. **References for the literature review see section 3.4.1. Background (page 27ff).**

3.13. Appendices

Additional documents added to ***online*** form:

- Paper Review as separate document
- Participant information sheet in English and German
- BESS information sheet to hand out to participant
- Informed consent sheet in English and German
- Project leader's CV

4. Curriculum Vitae / Lebenslauf

Name, Vorname	Beereuter, Patric
Geburtsdatum	1. Juni 1989
Heimatort und Kanton	Oberembrach ZH, Stadel ZH

Ausbildung:

• 1995-1997	Kindergarten Oberägeri
• 1997-2001	1.-4. Klasse Primarschule Oberägeri
• 2001-2002	5.-6. Klasse Primarschule Knonau
• 2002-2009	Langzeitgymnasium Kantonsschule Limmattal Schwerpunkt Biologie/Chemie
• 2006-2007	Austauschjahr in Manchester, England Besuch des Ashton-Under-Lyne Sixth Form College
• 2010-2015	Bachelor of Medicine mit Schwerpunkt Chiropraktik Universität Zürich
• 2015-	Master of Chiropractic Medicine Universität Zürich

5. Acknowledgments

I would like to thank Prof. Dr. Humphreys for the supervision of the project.

A special thank is deserved by Prof. Dr. Peterson for her help, her inputs and corrections on the project and literature review.

I would also like to thank Dr. Ruhe for the idea and assistance to start this study and for the work he has done on this subject in the past.

6. Appendix

Kantonale Ethikkomission
Stampfenbachstr. 21
8090 Zürich

Prof. Dr. Kim Humphreys
Universiätsklinik Balgrist
Forchstr. 340
8008 Zürich

Zürich, 20.7.2017

Betreff: Bitte um Überprüfung der folgenden Studie:

« Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability. »

Sehr geehrte Damen und Herren

Gerne senden wir Ihnen die Unterlagen zur Überprüfung unserer geplanten Studie zu. Ziel der Studie ist es die Praxistauglichkeit der «Advanced Gyroscope iPhone App» als Alternative oder Ergänzung zum «BESS» (Balance Error Scoring System) zu prüfen. Dies könnte eine einfache und zuverlässige Methode werden, die Balance einer Person zu messen oder im Verlauf zu verfolgen.

Die Studie wird als Doktorarbeit von Cand. Med. Patric Beereuter unter der Leitung und Betreuung von Prof. Dr. Kim Humphreys durchgeführt.

Mit freundlichen Grüssen

Prof. Dr. Kim Humphreys
Cand. Med. Patric Beereuter

Datum

_____

Unterschrift

_____

Unterschrift

_____

Kanton Zürich
Kantonale Ethikkommission

Prof. Dr. med. Erich W. Russi
Präsident Abteilung B

Dr. med. Peter Kleist
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Universitätsklinik Balgrist
Prof. Dr. Kim Humphreys
Forchstrasse 340
8008 Zürich

9. November 2017 / rlu

Erfüllung der Auflagen
BASEC-Nr. 2017-01354
Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.

Sehr geehrter Herr Prof. Humphreys

Wir beziehen uns auf die submission summary vom 02.11.2017.

Die in unserer Beschlussmitteilung vom 30.10.2017 formulierten Auflagen sind damit erfüllt.

Freundliche Grüsse

i.V.

Erich W. Russi

Peter Kleist

Beilage: submission summary dt. 02.11.2017

Teilnehmerinformationen

Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.

Projektleiter: Prof. Dr. Kim Humphreys

Lieber Teilnehmer/-in

Mit dieser Information möchten wir Sie über unsere Studie aufklären, um zwei Methoden zur Messung des Gleichgewichts auf festem und weichem Untergrund zu vergleichen. Vielen Dank, dass Sie an dieser Studie teilnehmen möchten.

Ziel der Studie

Das Ziel dieser Studie ist es herauszufinden, ob die Iphone Applikation «Advanced Gyroscope» eine objektive Messmethode für das Gleichgewicht bieten kann. Das BESS Protokoll tendiert zu Subjektivität und kann, falls von verschiedenen Testern durchgeführt, unterschiedliche Resultate produzieren. Falls das Gyroscope App zuverlässige Resultate liefern kann, könnte es in der Klinik und für Sportvereine (z.B. Eishockey) ein einfaches Hilfsmittel zum Messen des Gleichgewichtes werden. Mit diesem App könnte man allenfalls auch einen Baseline Test mit dem ganzen Team durchführen und im Falle einer Hirnerschütterung wiederholen, um allfällige Einflüsse zu messen.

Allgemeine Informationen

Im Ganzen werden 50 Freiwillige an dieser Studie teilnehmen. Diese Studie wird in Übereinstimmung mit der schweizerischen Gesetzgebung und nach international anerkannten Richtlinien durchgeführt. Sie wurde von der zuständigen, unabhängigen Ethikkommission des Kantons genehmigt.

Auswahl der Studienteilnehmer

Um an der Studie teilnehmen zu können müssen Sie folgende Kriterien erfüllen:

- O Sie sind zwischen 14 und 60 Jahre alt.
- O Sie hatten in den letzten 6 Monaten keine Hirnerschütterung.
- O Sie haben keine bekannte neurologische Erkrankung.
- O Sie haben keine Ihnen bekannte muskuloskelettale Verletzung, Erkrankung, oder Operation, die das Gleichgewicht beeinflussen.
- O Sie hatten in den letzten 6 Monaten keine Knie- oder Fussverletzung.

Freiwilligkeit der Teilnahme

Ihre Teilnahme an dieser Studie ist freiwillig. Sie dürfen zu jeder Zeit aus der Studie austreten, falls Sie sich unwohl fühlen oder Sie nicht möchten, dass Ihre Resultate für die Studie verwendet werden. Einen allfälligen Widerruf Ihrer Einwilligung bzw. den Rücktritt von der Studie müssen Sie nicht begründen.

Studienablauf

Um an dieser Studie teilzunehmen benötigen Sie einmalig etwa 30 Minuten Zeit. Während dieser einen Sitzung werden Sie durch 3 Durchgänge des BESS (Balance Error Scoring System) Protokolls geführt. Das Protokoll besteht aus 6 Standpositionen. Je 3 Positionen auf zwei unterschiedlichen Untergründen (hart und weich): Zweibeinstand, Einbeinstand und Tandemstand. Jede Standposition muss 20 Sekunden mit geschlossenen Augen und Händen an den Hüften gehalten werden.

Studienablauf	**Patient oder Examinator**	**Zeit**
1. Erklärung des BESS Protokolls und der Gyroscope iPhone App.	Examinator überreicht dem Teilnehmer das BESS Informationsblatt mit den Standpositionen und Fehlerkriterien und beantwortet allfällige Fragen. Zudem wird die Funktionsweise der Advanced Gyroscope Messungen erklärt.	5 min
2. Teilnehmerinformationen und Einverständniserklärung	Examinator notiert die nötigen Informationen über den Studienteilnehmer: • Alter, Geschlecht, Gewicht, Grösse, Sportarten • Auswahlkriterien Der Patient liest und unterschreibt die Einverständniserklärung.	5 min
3. Durchführung des BESS Protokolls ➔ 3-mal ➔ Jede Position wird 20 Sek. mit geschlossenen Augen und Händen an den Hüften gehalten ➔ Examinator startet vor jeder Position die Messung	3 Standpositionen auf hartem Untergrund (Boden): • Double Leg Stance • Single Leg Stance • Tandem Stance 3 Standposition auf weichem Untergrund (Schaumstoff): • Double Leg Stance • Single Leg Stance • Tandem Stance	3 x 5 min 15 min
4. Beendigung der Studie	Der Teilnehmer hat nun Zeit Fragen zu stellen oder Einblick in die Resultate zu erhalten.	5 min
Gesamtdauer		***ca. 30 min***

Risiken und Unannehmlichkeiten

Diese Studie birgt ein sehr kleines Risiko. Falls Sie sich unwohl fühlen, dürfen Sie jederzeit eine Pause einlegen oder aus sich aus der Studie zurückziehen. Es wird zu jeder Zeit jemand neben Ihnen stehen, falls Sie zu stark wanken oder zu fallen drohen.

Vertraulichkeit der Daten

Alle in dieser Studie gewonnen Informationen werden vertraulich behandelt. Ihre Daten werden mit einer Nummer verschlüsselt und sie werden in der Studie nicht persönlich identifiziert. Ihre verschlüsselten Informationen werden für wissenschaftliche Publikationen oder Präsentationen verwendet. Falls gewünscht, kann die Ethikkommission zu jeder Zeit Zugriff zu den Originaldaten erhalten. Ihr Name wird nie veröffentlicht.

Kosten

Durch die Teilnahme an dieser Studie entstehen Ihnen keine Kosten.

Nutzen

Die Teilnahme an dieser Studie bringt Ihnen keinen Nutzen.

Entschädigung für die Studienteilnahme

Für die Teilnahme an dieser Studie erhalten Sie keine Entschädigung.

Kontaktpersonen

Studienleitung:	Prof. Dr. Kim Humphreys kim.humphreys@balgrist.ch 00414438657012
Prüfperson:	Cand. Med. Patric Beereuter patric.beereuter@gmail.com 0041765739080

Participant Information

Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.

Projectleader: Prof. Dr. Kim Humphreys

Dear Participant/Volunteer

With this information letter, we would like to introduce you to our study to compare two methods that measure the balance on firm and on soft surface. Thank you for taking part in our study.

Aim

The aim is to find out whether the Advanced Gyroscope App could be a more objective measurement for postural stability. The BESS Protocol tends to be subjective and when performed by different people is likely produce different scores. If the Gyro App proves to be reliable and useful it could be beneficial to practices, sport teams (e.g. Ice Hockey) to have an objective way of measuring the postural stability. It might also be an option to do it as a baseline test in a team or in case of a concussion to see if there has been an impact on the postural stability.

General Information

A total of 50 people will take part in this study. This study will be conducted with respect to current Swiss law and international accepted guidelines for participation in research.

Participant Inclusion Criteria

To be included in our study you need to meet following criteria:

- You are between the age of 14 and 60.
- No history of concussion in the last 6 months.
- No known neurological disorder.
- No known muscosceletal injury, condition or surgery that affects your balance.
- No knee or ankle injury in the previours six months.

Voluntary Participation

Your participation in this study is optional. You are free to withdraw from this study during the procedure at any time if you feel any discomfort or if you do not want us to use your results in our research. You will not be asked to justify your reasons for withdrawing.

Course of the study

To participate in this study, you only need to attend about 30 minutes. During this appointment, you will be guided through 3 trials of the BESS (Balance Error Scoring System) protocol which contains a total of 6 stances. 3 different stances on two different surfaces (firm and soft): Double leg stance, single leg stance and tandem stance. Each of the stances should be maintained for 20 seconds with your eyes closed and hands rested on your hips.

Schedule the appointment	**Participant or Examiner action**	**Time**
1. Explanation of the BESS protocol and Gyroscope iPhone Application	Examiner hands over the BESS Information sheet with the stances and scoring explanation answers questions to the protocol and explains how the Gyroscope measurements work.	5 min
2. Participant Information and Informed Consent	Examiner notes the required participant information: • Age, Gender, Weight, Height, Sports • Inclusion criteria Participant reads and signs the Informed Consent document.	5 min
3. Conducting the BESS protocol ➔ 3 times ➔ each stance 20 seconds with eyes closed and hand on hips ➔ Examiner starts the Gyro measurement before each stance	3 stances on hard surface (floor): • Double Leg Stance • Single Leg Stance • Tandem Stance 3 stances on soft surface (foam) • Double Leg Stance • Single Leg Stance • Tandem Stance	3 x 5min 15 min
4. Termination of Study	Participant may ask questions or have a look at the results if requested.	5 min
Total Duration		***Approx. 30 min***

Risks and Discomfort

This study is of very low risk. But if you feel any discomfort during the protocol you are free to take a break or to withdraw at any time. There will always be someone standing next to you to help you in case you stumble during one of the stances.

Confidentiality

All personal data collected within this study is strictly confidential. You will not be identified personally. All data will be analysed and presented as a group and not individual identifiable. Your data will only be used for scientific publication or presentations. If requested, the ethic commission may have access to the original data. Your name will never be published.

Costs

There are no costs involved for you in participating in this study.

Benefit

There will be no benefit for you in participating in this study.

Compensation for participants

You will not receive any compensation for your participation.

Contact

Projectleader: Prof. Dr. Kim Humphreys
kim.humphreys@balgrist.ch
00414438657012

Examiner: Cand. Med. Patric Beereuter
patric.beereuter@gmail.com
0041765739080

Schriftliche Einwilligungserklärung zur Teilnahme an einem Studienprojekt

Bitte lesen Sie dieses Formular sorgfältig durch. Bitte fragen Sie, wenn Sie etwas nicht verstehen oder wissen möchten.

BASEC-Nummer (nach Einreichung):	2017-01354
Titel der Studie (wissenschaftlich und Laiensprache):	***Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability.***
verantwortliche Institution (Projektleitung mit Adresse):	Prof. Dr. Kim Humphreys Head Chiropractic Medicine University of Zürich Hospital Balgrist Forchstrasse 340, 8008 Zürich 00414438657012
Ort der Durchführung:	Poliklinik für Chiropraktische Medizin Universitätsklinik Balgrist
Leiter / Leiterin der Studie am Studienort: Name und Vorname in Druckbuchstaben:	Prof. Dr. Kim Humphreys
Teilnehmerin/Teilnehmer: Name und Vorname in Druckbuchstaben: Geburtsdatum:	☐ weiblich ☐ männlich

- Ich wurde vom unterzeichnenden Prüfperson mündlich und schriftlich über den Zweck, den Ablauf des Projekts, über mögliche Vor- und Nachteile sowie über eventuelle Risiken informiert.
- Ich nehme an diesem Projekt freiwillig teil und akzeptiere den Inhalt der zum oben genannten Projekt abgegebenen schriftlichen Information. Ich hatte genügend Zeit, meine Entscheidung zu treffen.
- Meine Fragen im Zusammenhang mit der Teilnahme an diesem Projekt sind mir beantwortet worden. Ich behalte die schriftliche Information und erhalte eine Kopie meiner schriftlichen Einwilligungserklärung.

- Ich bin einverstanden, dass die zuständigen Fachleute der Projektleitung/des Auftraggebers der Studie und der für dieses Projekt zuständigen Ethikkommission zu Prüf- und Kontrollzwecken in meine unverschlüsselten Daten Einsicht nehmen dürfen, jedoch unter strikter Einhaltung der Vertraulichkeit.
- Bei Studienergebnissen oder Zufallsbefunden, die direkt meine Gesundheit betreffen, werde ich informiert. Wenn ich das nicht wünsche, informiere ich meinen Prüfarzt.
- Die Haftpflichtversicherung der Uniklinik Balgrist kommt für allfällige Schäden auf.

Ort, Datum	Unterschrift Teilnehmerin/Teilnehmer

Bestätigung der Prüfperson:

Hiermit bestätige ich, dass ich dieser Teilnehmerin/diesem Teilnehmer Wesen, Bedeutung und Tragweite des Projekts erläutert habe. Ich versichere, alle im Zusammenhang mit diesem Projekt stehenden Verpflichtungen gemäss des geltenden Rechts zu erfüllen. Sollte ich zu irgendeinem Zeitpunkt während der Durchführung des Projekts von Aspekten erfahren, welche die Bereitschaft der Teilnehmerin/des Teilnehmers zur Teilnahme an der Studie beeinflussen könnten, werde ich sie/ihn umgehend darüber informieren.

Ort, Datum	Name und Vorname Prüfperson in Druckbuchstaben Unterschrift der Prüfperson

7. Declaration of Originality / Erklärung

Masterarbeit

Ich erkläre ausdrücklich, dass es sich bei der von mir im Rahmen des Studiengangs Master of Chiropractic Medicine (M Chiro Med) der Medizinischen Fakultät der Universität Zürich eingereichten schriftlichen Arbeit mit dem Titel:

Protocol for a clinical study to compare the Balance Error Scoring System (BESS) with Advanced Gyroscope (iPhone App) Measurements for measuring postural stability,

um eine von mir selbst und ohne unerlaubte Beihilfe sowie *in eigenen Worten* verfasste Masterarbeit* handelt.

Ich bestätige überdies, dass die Arbeit als Ganzes oder in Teilen weder bereits einmal zur Abgeltung anderer Studienleistungen an der Universität Zürich oder an einer anderen Universität oder Ausbildungseinrichtung eingereicht worden ist.

Verwendung von Quellen

Ich erkläre ausdrücklich, dass ich *sämtliche* in der oben genannten Arbeit enthaltenen Bezüge auf fremde Quellen (einschliesslich Tabellen, Grafiken u. Ä.) als solche kenntlich gemacht habe. Insbesondere bestätige ich, dass ich *ausnahmslos* und nach bestem Wissen sowohl bei wörtlich übernommenen Aussagen (Zitaten) als auch bei in eigenen Worten wiedergegebenen Aussagen anderer Autorinnen oder Autoren (Paraphrasen) die Urheberschaft angegeben habe.

Sanktionen

Ich nehme zur Kenntnis, dass Arbeiten, welche die Grundsätze der Selbstständigkeits-erklärung verletzen – insbesondere solche, die Zitate oder Paraphrasen ohne Herkunftsangaben enthalten –, als Plagiat betrachtet werden und die entsprechenden rechtlichen und disziplinarischen Konsequenzen nach sich ziehen können (gemäss §§ 7ff der Disziplinarordnung der Universität Zürich sowie §§ 51ff der Rahmenverordnung für das Studium in den Bachelor- und Master-Studiengängen an der Medizinischen Fakultät der Universität Zürich).

Ich bestätige mit meiner Unterschrift die Richtigkeit dieser Angaben.

Datum:

Name: *Beereuter* Vorname: *Patric*

Unterschrift:……..

* Falls die Masterarbeit eine Publikation enthält, bei der ich Erst- oder Koautor/-in bin, wird meine eigene Arbeitsleistung im Begleittext detailliert und strukturiert beschrieben.